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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is:

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

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Contact Person:

Wu Zicui Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: February 19, 2014

2. <u>Device Name</u>: M9/M9T/M9CV Diagnostic Ultrasound System

Classification

Regulatory Class: II Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)

3. Device Description:

M9/M9T/M9CV is a software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B-Mode, M-Mode, PW-Mode, Color-Mode, Power/Dirpower Mode, THI, iScape mode, Color M, Elastography, LVO or the combined mode (i.e. B/M-Mode, B/PW-mode, B/PW/Color).

This system is a Track 3 device that employs an array of probes that include linear array and convex array with a frequency range of approximately 3.0 MHz to 10.0

MHz.

4. Intended Use:

The M9/M9CV/M9T Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, trans-esoph.(Cardiac), peripheral vessel, urology exams.

5. Comparison with Predicate Devices:

M9/M9T/M9CV Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate - Device .	Manufacturer	Model	510(k) Control
1	Mindray	DC-8	K132341
2	Mindray	M7	K131690
3	GE	Voluson E8	K101236

M9/M9T/M9CV has the same technological characteristics, is comparable in key safety and effectiveness features, and has the same intended uses and basic operating modes as the predicate devices. All systems transmit ultrasonic energy into patients and perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

 Subject device M9/M9T/M9CV has the same intended uses as the predicated device DC-8(K132341)

Subject Device	Predicate device
M9/M9T/M9CV	DC-8 (K132341)
The M9/M9CV/M9T Diagnostic Ultrasound	The DC-8/DC-8 PRO/DC-8 CV/DC-8
System is applicable for adults, pregnant	EXP/DC-8S diagnostic ultrasound system is
women, pediatric patients and neonates. It is	applicable for adults, pregnant women, pediatric
intended for use in fetal, abdominal, pediatric,	patients and neonates. It is intended for use in
small organ(breast, thyroid, testes), neonatal	fetal, abdominal, pediatric, small organ (breast,
and adult cephalic, trans-rectal, trans-vaginal,	thyroid, testes), neonatal cephalic, adult
musculo-skeletal(conventional, superficial),	cephalic, trans-rectal, trans-vaginal,
adult and pediatric cardiac,	musculo-skeletal (conventional, superficial),
trans-esoph.(Cardiac), peripheral vessel ,	cardiac adult, cardiac pediatric, peripheral
urology exams.	vessel, urology and transesophageal (Cardiac)
	exams.

- All of the patient contact material of the M9/M9T/M9CV are the same as that of the
 predicated device DC-8(K132341) and the predicated device M7(K131690) with the
 exception of the materials for probe SP5-1s. Materials for the SP5-1s are tested under
 ISO 10993-1 for its biocompatibility.
- The acoustic power levels of M9/M9T/M9CV are below the limits of FDA, which is the same as the predicated device DC-8(K132341).
- M9/M9T/M9CV is designed in compliance with the FDA recognized electrical and physical safety standard, which is the same as the predicated device DC-8(K132341).
- M9/M9T/M9CV has the same imaging modes as the predicated device DC-8(K132341): B, M, Color Doppler, PWD, CWD, Amplitude Doppler, Color M, Anatomical M Mode and combined mode).
- M9/M9T/M9CV has some special functions: iScape, TDI, TDI QA, LVO, Elastography, Stress Echo, Tissue Tracking QA, iWorks, iNeedle and IMT. All of them are identical as the predicated device DC-8(K132341).
- M9/M9T/M9CV has the same capacity in term of making comments and body marks on the images, reporting patient exam results as the predicated device DC-8(K132341).
- M9/M9T/M9CV has similar probes as the predicated device DC-8(K132341) and M7(K131609):

Subject device	Predicated device	Predicated device	NOTE
M9/M9T/M9CV	DC-8(K132341)	M7(K131690)	
C5-1s	C5-2E		They have same indications for use, mode of operation, array elements. Different design is intended to improve penetrability and spacial resolution. C5-1s probe has been tested under the IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37. Differences do not influence the safety and effectiveness of this probe.
L12-4s	/	L12-4s	Same.
P10-4s	P10-4E	/	Same (except for the shape
			of the socket which does
			not affect the performance
		·	of the probe).
P7-3Ts	1	P7-3Ts	Same.

L14-6Ns	/	L14-6Ns	Same.
V11-3Ws	V11-3WE	/	Same (except for the shape of the socket which does not affect the performance of the probe).
C11-3s	C11-3E		Same (except for the shape of the socket which does not affect the performance of the probe).
CW2s	CW2s	1	Same.
CW5s	CW5s	1	Same.
SP5-1s	P4-2NE P4-2E	/	SP5-1s has the same indications for use and performance specification with P4-2NE, except that indications for use Neonatal Cephalic is substantially equivalent to P4-2E.

 M9/M9T/M9CV has the same measurement and calculation functions as the predicated device DC-8(K132341) except for the cardiac measurement and calculation MV ALL which is equivalent to predicated device Voluson E8(101236).

6. Non-clinical Tests:

M9/M9T/M9CV Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been designed to conform with applicable medical safety standards. This device has been tested and evaluated under the following standards:

- UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.
- UD 3 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AAMI / ANSI ES60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility Requirements and tests (Edition 3)
- IEC 60601-2-37 Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- ISO14971 Medical devices Application of risk management to medical devices
- ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and

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testing within a risk management process

- IEC 62366 Medical devices Application of usability engineering to medical devices
- IEC 62304 Medical device software Software life cycle processes

 These non-clinical tests relied on in this premarket notification submission can support the determination of substantial equivalence of the subject device.

7. Clinical Studies

Not applicable. The subject of this submission, M9/M9T/M9CV Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the M9/M9T/M9CV Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

May 14, 2014

Shenzhen Mindray Bio-Medical Electronics, Co. Ltd.

% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K141010

Trade/Device Name: M9 Diagnostic Ultrasound System, M9T Diagnostic Ultrasound

System, M9CV Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: 11

Product Code: IYN, IYO, ITX

Dated: April 24, 2014 Received: April 25, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the M9 Diagnostic Ultrasound System, M9T Diagnostic Ultrasound System, M9CV Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

C11-3s	C5-1s	L12-4s
P7-3Ts	SP5-1s	P10-4s
L14-6Ns	V11-3Ws	CW2s
CW5s		

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine Morris

Director

Division of Radiological Health Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

for

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017

illulcations for use		See FIXA Statement on last page.
510(k) Number (if known)		
K141010		
Device Name		
M9/M9T/M9CV		
ndications for Use (Describe)		
The M9/M9CV/M9T Diagnostic Ultrasound System is applicable for intended for use in fetal, abdominal, pediatric, small organ(breast, thy vaginal, musculo-skeletal(conventional, superficial), adult and pediatric exams.	roid, testes), neonatal a	nd adult cephalic, trans-rectal, trans-
•		
·		
•		
ype of Use (Select one or both, as applicable)		
Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Coun	ter Use (21 CFR 801 Subpart C)
PLEASE DO NOT WRITE BELOW THIS LINE - CO	ONTINUE ON A SEP	ARATE PAGE IF NEEDED.
FOR FDA U	SE ONLY	
Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)	
Smh.	7)	
•	/ *	
•		2007

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Diagnostic Ultrasound Indications For Use Format

System:

M9/M9T Diagnostic Ultrasound System

Transducer:

N/A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Appli	Clinical Application		Mode of Operation									
General (Track I Only)	Specific (Track & 3)	В	м	PWD	CWD	Color Doppler		Combined (specify)	Other (specify)			
Ophthalmic	Ophthalmic							Î				
	Fetal	Ν	N	N		N	N	N	Note 1, 2,4,5			
	Abdominal	Z	N	N	N	N	N	N	Note 1, 2,4,5			
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric	Z	N	N	N	N	N	N	Note 1, 2,4,5			
•	Small Organ (Specify**)	Z	N	N		N	N	N	Note 1,2,5,6			
Fetal Imaging	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,2,4,5			
retat imaging & Other	Adult Cephalic	N	Z	N	Z	N	N	N	Note 1, 2,4,5			
& Other	Trans-rectal	Z	N	N		N	N	N	Note 1,2,4,5			
	Trans-vaginal	Ν	N	N		N	N	N	Note 1, 2,4,5			
	Trans-urethral		L									
	Trans-esoph. (non-Card.)		L	<u> </u>					<u> </u>			
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,4,5			
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2,5			
-	Intravascular											
	Cardiac Adult	N	N	N	N	N	N	N	Note 1,2,3,4,5,7			
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,2,3,4,5			
Cardiac	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)	N	N	N	N	N	N.	N	Note 1, 3,4			
	Intra-cardiac											
Peripheral	Peripheral vessel	N	N	N		N	N	N	Note 1,2,4,5			
vessel	Other (Specify***)	N	N	N		N	N	N	Note 1,2,4,5			

N=new indication: P=previously cleared by FDA E=added under Appendix E

Additional comments: Combined modes-B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: iScape

Note 3:TDI

Note 4: Color M

Note5: Biopsy Guidance

Note6: Elastography

Note7: Contrast imaging (Contrast agent for LVO)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

M9/M9T Diagnostic Ultrasound System

Transducer: C11-3s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation							
General						Color	Amplituda	Combined	
(Track 1	Specific (Track 1 & 3)	В	М	PWD	CWD	Doppler	Doppler	(specify)	Other (specify)
Only)						Doppio.	Doppiei	(specify)	
Ophthalmic	Ophthalmic								
	Fetal				<u> </u>				
	Abdominal	N	N	N		N	N	N	Note 1,2,4,5
	Intra-operative (Specify*)								
	Intra-operative (Neuro)				<u> </u>				
	Laparoscopic		L	ļ					
	Pediatric	N	N	N		N	N	N	Note 1,2,4,5
	Small Organ (Specify**)	<u> </u>	<u> </u>						
Fetal Imaging	Neonatal Cephalic	N	N	N	<u> </u>	N	N	N	Note 1,2,4,5
& Other	Adult Cephane	٠			L			L	
oc Omer .	Trans-rectal				<u> </u>				
	Trans-vaginal								
	Trans-urethral	<u> </u>			ļ				
	Trans-esoph. (non-Card.)	<u> </u>	ļ	ļ	ļ				
	Musculo-skeletal				l				
	(Conventional)	<u> </u>			ļ			<u> </u>	
	Musculo-skeletal (Superficial)	<u> </u>	ļ	ļ				<u> </u>	
	Intravascular	_			ļ			<u> </u>	
	Cardiac Adult				L				
	Cardiac Pediatric	N	N	N		N	N	N	Note 1,2,4,5
Cardiac	Intravascular (Cardiac)		L						
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	N	Ñ	N		N	N	N	Note 1,2,4,5
vessel	Other (Specify***)								
N=new indica	tion: P=previously cleared by I	DA:	E=0	added u	nder A	pendix E			
Additional co	mments: Combined modesB+	M、	PW+	B、Col	or + B.	Power +	B、PW+C	olor+ B、Po	wer + PW +B.
	ntraoperative includes abdomina								
	Small organ-breast, thyroid, test				•		-		· · · · · · · · · · · · · · · · · · ·
	Other use includes Urology.								
	te 1: Tissue Harmonic Imaging.	The	featu	re does	not use	contrast a	ecnts.		
	te 2: iScape								
	te 3:TDI								
	te 4: Color M			-			·		
	te5: Biopsy Guidance								
							.	.	
	te6: Elastography		. fa-	LVO					
No	ne7: Contrast imaging (Contrast NOT WRITE BELOW THIS I	agen	CON	LVO)	CON A	NOTHER	DAGE NEI	(DED)	
					ONA	NOTHER	FAGE NEI	:DGD)	
Concurrence	of CDRH, Office of Device Ev	/B108	tton(ODE)					

M9/M9T Diagnostic Ultrasound System

Transducer: C5-1s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal	N	N	N		N	N	N	Note 1,2,4,5
	Abdominal	Z	N	N		N	N	N	Note 1,2,4,5
	Intra-operative (Specify*)			-					
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Ν	N	N		N	N	N	Note 1,2,4,5
	Small Organ (Specify**)								
D-4-3 3	Neonatal Cephalic								
Fetal Imaging	Adult Cephalic								
& Other	Trans-rectal							,	
	Trans-vaginal								
	Trans-urethral							<u> </u>	
	Trans-esoph. (non-Card.)							<u> </u>	
	Musculo-skeletal	N	N	N		N	N	N	Note 1,2,4,5
	(Conventional)	14	14		<u> </u>	14		<u>'`</u>	11010 1121713
	Musculo-skeletal (Superficial)								
	Intravascular								
	Cardiac Adult							<u> </u>	
	Cardiac Pediatric								
Cardiac	Intravascular (Cardiac)				I				
ı	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	N	N	N		N	N	N	Note 1,2,4,5
vessel	Other (Specify***)								
	tion: P=previously cleared by I	DA	E=	added u	nder A	opendix E			
Additional co	mments: Combined modesB+	M.	PW+	B、Col	от + В.	Power +	B、PW+C	olor+ B. Po	ower + PW +B.
	ntraoperative includes abdomina							_	
	Small organ-breast, thyroid, test		-						
	Other use includes Urology.								
	te 1: Tissue Harmonic Imaging.	The	featu	re does	not use	contrast a	gents.		
	te 2: iScape	- 110						· · · · · · · · · · · · · · · · · · ·	·
	ite 3:TDI								
	ite 4: Color M	-							· · · · · · · · · · · · · · · · · · ·
	nte5: Biopsy Guidance								
	te6: Elastography								
			. fo-	LVO					
NO	ote7: Contrast imaging (Contrast NOT WRITE BELOW THIS L	ager	CON	LYU)	CONIA	NOTHER	DACE NE	DED)	
					UN A	HOINER	I AUE NEI	JUDU)	
Concurrence	of CDRH, Office of Device Ev	aiva	tion(OUE)					

System: M9/M9T Diagnostic Ultrasound System

Transducer: L12-4s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	linical Application	Mode of Operation							
General	1					0.1			
(Track 1	Specific (Track 1 & 3)	В	М	PWD	CWD	Color		Combined	Other (specify)
Only)						Doppler	Doppler	(specify)	
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	۴	Р	P		P	Р	P	Note 1,2,5
1	Intra-operative (Specify*)								
ľ	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Р	P	P		P	Р	P	Note 1.2,5
	Small Organ (Specify**)	P	P	P		Р	P	Р	Note 1.2,5,6
Fetal Imaging	Neonatal Cephalic	P	P	Р		Р	. Р	. Р	Note 1,2,5
& Other	Adult Cephalic		<u> </u>	L					
- 50N	Trans-rectal		<u> </u>						
	Trans-vaginal		<u> </u>	ļ					
	Trans-urethral		ļ						
	Trans-esoph. (non-Card.)						ļ		
	Musculo-skeletal	P	P	Р		P	P	P	Note 1,2,5
	(Conventional)		Ļ					<u>;</u>	
	Musculo-skeletal (Superficial)	P	P	Р		P	Р	P	Note 1.2,5
	Intravascular		 						
	Cardiac Adult		<u> </u>						
	Cardiac Pediatric		<u> </u>						
Cardiac	Intravascular (Cardiac)								
1	Trans-esoph. (Cardiac)		<u> </u>						
i	Intra-cardiac			1					
Peripheral	Peripheral vessel	P	P	P		P	Р	Р	Note 1,2,5
vessel	Other (Specify***)								
N=new indica	tion: P=previously cleared by I	DA:	E=:	added u	nder Aj	ppendix E			
Additional co	mments: Combined modesB+	М、	PW+	B、Col	or + B.	Power +	B、PW+C	olor+ B、Pc	wer + PW +B.
*!	ntraoperative includes abdomina	ıl, the	огасіс	and v	ascular.				
**	Small organ-breast, thyroid, test	es.							
**	Other use includes Urology.								
	ne 1: Tissue Harmonic Imaging.	The	featu	re docs	not use	contrast a	gents.		
	te 2: iScape								
	ite 3:TDI								
No	Note 4: Color M								
No	Note5: Biopsy Guidance								
	te6: Elastography								
	te7: Contrast imaging (Contrast	agen	ıt for	LVO)		•			
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
	Concurrence of CDRH, Office of Device Evaluation(ODE)								
				_,					

M9/M9T Diagnostic Ultrasound System

Transducer: P7-3Ts
Intended Use: Diagnostic ultra

Clinical Application				Mode of Operation								
General Track 1 Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic	Ophthalmic											
	Fetal											
	Abdominal											
	Intra-operative (Specify*)											
	Intra-operative (Neuro)											
	Laparoscopic					•						
	Pediatric											
	Small Organ (Specify**)											
etal Imaging	Neonatal Cephalic											
k Other	Adult Cephalic		Щ	L					<u> </u>			
Comer	Trans-rectal											
	Trans-vaginal											
	Trans-urethral							<u> </u>				
	Trans-csoph. (non-Card.)											
	Musculo-skeletal			1]				
	(Conventional)											
	Musculo-skeletal (Superficial)							<u> </u>				
	Intravascular											
	Cardiac Adult .											
	Cardiac Pediatric								•			
Cardiac	Intravascular (Cardiac)											
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P	Note 1, 3,4			
	Intra-cardiac											
Peripheral	Peripheral vessel											
essel .	Other (Specify***)								-			
N=new indica	tion: P=previously cleared by I	DA:	E=:	added u	nder A	opendix E						
Additional cor	mments: Combined modes-B+	M. I	PW+	B、Col	or + B.	Power +	B、PW+C	olor+ B、Pa	wer + PW +B.			
	ntraoperative includes abdomina											

Additional comments: Combined modes-B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.
*Intraoperative includes abdominal, thoracic, and vascular.
**Small organ-breast, thyroid, testes.
***Other use includes Urology.
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.
Note 2: iScape
Note 3:TDI
Note 4: Color M
Note5: Biopsy Guidance
Note6: Elastography
Note7: Contrast imaging (Contrast agent for LVO)
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Concurrence of CDRH, Office of Device Evaluation(ODE)

M9/M9T Diagnostic Ultrasound System

Transducer: SP5-1s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application Mode of Operation								
General						Color	Amplitude	Combined	
(Track 1	Specific (Track 1 & 3)	В	M j	PWD	CWD		Doppler	Combined	Other (specify)
Only)						Doppler	Dobbiei	(specify)	
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	Z	N	N	N	N	N	N	Note 1,2,4,5
	Intra-operative (Specify*)								
l	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Z	N	N	N	N	N	N	Note 1,2,4,5
ł	Small Organ (Specify**)								·
Eatal Imagina	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,2,4,5
Fetal Imaging & Other	Adult Cephalic	N	N	N	N	N	N	N	Note 1,2,4,5
& Other	Trans-rectal				<u> </u>				
	Trans-vaginal	ļ							
	Trans-urethral								
	Trans-esoph. (non-Card.)	<u> </u>	<u> </u>	<u>.</u>	<u> </u>		<u> </u>		
	Musculo-skeletal								
	(Conventional)				<u>. </u>				
	Musculo-skeletal (Superficial)								
	Intravascular								
	Cardiac Adult	N	N	N	N	N	N	N	Note 1,2,3,4,5,7
İ	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,2,3,4,5
Cardiac	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)				· · · · _				
	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel	Other (Specify***)								
N=new indica	ntion: P=previously cleared by I	DA.	E=:	added u	nder A	opendix E		4	
Additional co	mments: Combined modesB+	М	PW+	B、Col	or + B	Power +	B、PW +C	olor+ B、Po	ower + PW +B.
	ntraoperative includes abdomina								
**	Small organ-breast, thyroid, test	es.							
	*Other use includes Urology.								
	ote 1: Tissue Harmonic Imaging.	The	fcatu	re does	not use	contrast a	igents.		
	ote 2: iScape								
	ote 3:TDI								
No	ote 4: Color M								
	ote5: Biopsy Guidance								
	ote6: Elastography								
	ote7: Contrast imaging (Contrast	ager	ıı for	LVO)					
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	of CDRH, Office of Device Ev								_

M9/M9T Diagnostic Ultrasound System

Transducer: P10-4s

Clinical Application

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

					_				
General (Track I Only)	Specific (Track 1 & 3)	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal .	Z	N	N	N	N	N	N	Note 1,4
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1,4
	Small Organ (Specify**)								
Fetal Imaging	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,4
ectar imaging & Other	Adult Cephalic								
& Offici	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)			L					
•	Musculo-skeletal			1				i l	
	(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Cardiac Adult		L						- '
	Cardiac Pediatric	N	N	N	N	Z	N	N	Note 1, 3,4
Cardiac	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel	Other (Specify***)							,	
N=new indica	tion; P=previously cleared by f	DA:	E=8	added u	nder Ar	pendix E			•
	nments: Combined modesB+						B、PW+C	olor+ B、Po	ower + PW +B.
	ntraoperative includes abdomina		_						
	Small organ-breast, thyroid, test			•	···				
	Other use includes Urology.								
	te 1: Tissue Harmonic Imaging.	The	featu	re does	not use	contrast a	gents.		_
	te 2: iScape						_		
	te 3:TDI								· · · · · · ·
	te 4:Color M						· · · · · ·		
	te5: Biopsy Guidance								
	te6: Elastography								
	te7: Contrast imaging (Contrast	agen	ı for	LVO					
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<u> </u>	of CDRH, Office of Device Ev				JIVA	·VIIILAN		,	

M9/M9T Diagnostic Ultrasound System

Transducer: L14-6Ns

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Diagnostic ultrasound imaging	OT II	ula II	ow ana	INSIS OF				·		
	linical Application	Mode of Operation									
General (Track I Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)		
Ophthalmic	Ophthalmic		Ĺ_								
-	Fetal										
	Abdominal	P	Р	Р		P	P	P	Note 1,2,5		
	Intra-operative (Specify*)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric	P	Р	P		Р	P	P	Note 1,2,5		
	Small Organ (Specify**)	Р	Р	P		P	P	P	Note 1,2,5,6		
Fetal Imaging	Neonatal Cephalic	P	Р	P		P	Р	P	Note 1,2,5		
& Other	Adult Cephalic										
ac Offici	Trans-rectal										
	Trans-vaginal										
	Trans-urethral		<u> </u>						· · · · · · · · · · · · · · · · · · ·		
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2,5		
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2,5		
	Intravascular					<u> </u>					
	Cardiac Adult										
	Cardiac Pediatric										
Cardiac	Intravascular (Cardiac)										
	Trans-esoph. (Cardiac)										
	Intra-cardiac										
Peripheral	Peripheral vessel	P	P	P		P	P	P	Note 1,2,5		
vessel	Other (Specify***)						_				

Namew indication. Panreviously cleared by FDA. Fadded under Appendix E.

M-IICM II	suication; P-previously cleared by PDA E-added under Appendix E
Additions	al comments: Combined modesB+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.
	*Intraoperative includes abdominal, thoracic, and vascular.
	**Small organ-breast, thyroid, testes.
	***Other use includes Urology.
	Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.
	Note 2: iScape
	Note 3:TDI
	Note 4: Color M
	Note5: Biopsy Guidance
	Note6: Elastography

Note7: Contrast imaging (Contrast agent for LVO)

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M9/M9T Diagnostic Ultrasound System

Transducer: V11-3Ws

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation							
General (Track I Only)	Specific (Track 1 & 3)	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal	Ν	N	N		N	N	N	Note 1,2,4,5
	Abdominal		\Box						•
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic				·				
	Pediatric							L	
	Small Organ (Specify**)								
	Neonatal Cephalic		<u> </u>			<u> </u>			
Fetal Imaging & Other	Adult Cephane		<u> </u>						
& Other	Trans-rectal	N	N	N		N	N	N	Note 1,2,4,5
	Trans-vaginal	N	N	N	<u> </u>	N	N	N	Note 1, 2,4.5
	Trans-urethral		<u> </u>						
	Trans-esoph. (non-Card.)		<u> </u>		<u> </u>			<u> </u>	
	Musculo-skeletal	·	1		ļ .	<u> </u>	']	
	(Conventional)		ــــــ		<u> </u>	ļ		ļ	
	Musculo-skeletal (Superficial)	<u> </u>	<u> </u>						
	Intravascular	<u> </u>							
	Cardiac Adult				1			<u> </u>	
	Cardiac Pediatric	<u> </u>							
Cardiac	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac	<u> </u>							
Peripheral	Peripheral vessel								
vessel	Other (Specify***)	Ν	N	N		N	N	N	Note 1,2,4,5
N=new indica	ition: P=previously cleared by I	DA	E≠r	added u	nder A	ppendix E	•		
Additional cor	mments: Combined modesB+	М、	PW+	B、Col	or + B.	Power +	B、PW+C	olor+ B、Po	wer + PW +B.
	ntraoperative includes abdomina								
	Small organ-breast, thyroid, test								
	*Other use includes Urology.								
	ite 1: Tissue Harmonic Imaging.	The	featu	re does	not use	contrast a	gents.	•••	-
	ite 2: iScape								
	nte 3: TDI								
	te 4: Color M					-		•	-
	te5: Biopsy Guidance								
	te6: Elastography								
	te7: Contrast imaging (Contrast	90er	ı for	I VO					
1117	nor, contrast magnig (contrast								
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System: M9/M9T Diagnostic Ultrasound System

Transducer: CW2s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Mode of Opera							of Operation	on	
General			I			Cal	A	CL!1	
(Track !	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Doppler	Combined (specify)	Other (specify)
Only)						Doppiei	Dopplet	(specify)	
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative (Specify*)								<u> </u>
1	Intra-operative (Neuro)						ļ		
	Laparoscopic		<u> </u>						
	Pediatric			<u> </u>	Р				
	Small Organ (Specify**)		<u> </u>			_			
Fetal Imaging	Neonatal Cephalic		ļ						
& Other	Adult Cephalic		<u> </u>	ļ	P				
C 011101	Trans-rectal •		ļ		<u></u>				
	Trans-vaginal								
	Trans-urethral			ļ					
	Trans-esoph. (non-Card.)		<u> </u>	ļ					
	Musculo-skeletal								
	(Conventional)			ļ				<u> </u>	
	Musculo-skeletal (Superficial)			ļ					
	Intravascular			ļ					
	Cardiac Adult		L	ļ	Р				
	Cardiac Pediatric				Р				
Cardiac	Intravascular (Cardiac)			ļ					
	Trans-esoph. (Cardiac)		L	<u> </u>					
	Intra-cardiac								
Peripheral	Peripheral vessel				P				
vessel	Other (Specify***)							,	
	tion: P=previously cleared by F								
Additional cor	nments: Combined modesB+	М、	PW+	B、Col	or + B.	Power +	B、PW+C	olor+ B、Pe	ower + PW +B.
*11	ntraoperative includes abdomina	l, the	oracio	, and v	ascular.				
••5	Small organ-breast, thyroid, teste	es.					,		
	Other use includes Urology.								
No	te 1: Tissue Harmonic Imaging.	The	featu	re does	not use	contrast a	gents.		
No	te 2: iScape								
	te 3:TDI								
	te 4: Color M								
	te5: Biopsy Guidance								
	te6: Elastography								
	te7: Contrast imaging (Contrast	agen	t for	LVO)					***
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M9/M9T Diagnostic Ultrasound System

Transducer: CW5s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application	Mode of Operation								
General (Track I Only)	Specific (Track I & 3)	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
-	Fetal									
	Abdominal									
	Intra-operative (Specify*)							•		
	Intra-operative (Neuro)			L						
	Laparoscopic		<u> </u>							
	Pediatric				Р					
	Small Organ (Specify**)		<u> </u>	ļ <u>.</u>						
Fetal Imaging	Neonatal Cephalic		<u> </u>							
retai imaging & Other	Adult Cephalic			<u> </u>						
& Other	Trans-rectal		<u> </u>	ļ	1			ļ		
	Trans-vaginal		ļ		ļ					
	Trans-urethral		 		!			L		
	Trans-esoph. (non-Card.)		ļ							
	Musculo-skeletal		ŀ	Ì			1	,		
	(Conventional)				ļ			<u> </u>		
	Musculo-skeletal (Superficial)		<u> </u>	<u> </u>	<u> </u>	ļ				
	Intravascular				<u> </u>			ļ		
	Cardiac Adult			<u> </u>	L		<u> </u>			
	Cardiac Pediatric			<u> </u>	P					
Cardiac	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)	,								
	Intra-cardiac									
Peripheral	Peripheral vessel				T]				
vessel	Other (Specify***)		1							
N=new indica	ation: P=previously cleared by I	'nA.	E=	added u	inder A	ppendix E				
Additional co	mments: Combined modesB+	M.	PW+	B. Co	lor + B	Power +	B、PW+C	olor+B、P	ower + PW +B.	
	ntraoperative includes abdomina									
**	Small organ-breast, thyroid, test	es.								
	*Other use includes Urology.									
	ote 1: Tissue Harmonic Imaging.	The	featu	re does	not use	contrast s	gents.			
	ote 2: iScape									
	ote 3:TDI									
	nte 4: Color M							· · · · · · · · · · · · · · · · · · ·		
	ote5: Biopsy Guidance									
	ote6: Elastography									
	ote7: Contrast imaging (Contrast	aper	nt for	LVO					·	
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